

REMARKS

Claim 47 has been amended to specify that the claimed wound dressing consists essentially of a gauze matrix and cross-linked dextran beads in powder form on a particular wound-contacting side of the gauze. Support for this amendment can be found at, e.g., page 25, lines 7-9. No new matter has been added. Thus, claims 47-53 are pending.

Applicants thank the Examiner for the courtesy of a telephone interview on December 13, 2005, in which the double patenting rejection was discussed as described below.

Rejection under 35 U.S.C. § 112

The Examiner rejected claims 47-53 as indefinite regarding the language "sprayed as a layer." Applicants have amended claim 47 to remove the language regarding sprayed as a layer. The Examiner is requested to withdraw the rejection under 35 U.S.C. § 112 for indefiniteness.

Finality of Office Action

The Examiner made the present action final, despite a new double-patenting rejection over co-pending Application Ser. No. 11/145,678 ("the '678 Application;" Attorney Docket No. 14004-017002), stating that the Applicants were under an obligation to cite this later-filed application in the instant application and that their failure to do so resulted in the new rejection. See Office Action at page 8. The Examiner asserted that the "[a]pplicants will not be permitted to extend the prosecution of the present application by reason of their inaction with regard to notice to the Office of conflicting claims in a copending application." Therefore, according to the Examiner, finality is proper because Applicants caused the rejection by such inaction, "the discovery of which necessitated the new grounds of rejection at this advanced point in prosecution."

While the Examiner recognized that copending '678 Application is related to the instant application, the Examiner failed to note that Applicants filed a preliminary amendment on June 6, 2005, coincident with the filing of the '678 Application. June 6, 2005 is well before the date of the present office action. The preliminary amendment canceled the parent claims and set forth

only method claims. Applicants did not cause the rejection by any alleged "inaction" on their part. Rather, Applicants avoided such a rejection by setting forth claims from a different restriction group. See, Office Action mailed November 28, 2000. Thus, as the rejection is both new and not precipitated by any action or inaction on the part of the Applicants, the finality of the Office Action is improper. See MPEP § 706.07(a). Applicants request that the finality of the previous office action withdrawn.

Double Patenting Rejection

The Examiner provisionally rejected claims 47-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 72-84 of copending Application No. 10/334,864 (Attorney Docket No. 14004-005001). Applicants submit that the pending claims in copending Application No. 10/334,864 do not conflict with and are patentably distinct from the pending claims of the instant application. In the interests of advancing prosecution, however, Applicants submit herewith a terminal disclaimer with respect to Application No. 10/334,864.

The Examiner provisionally rejected claims 47-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9, 11, and 24-28 of copending Application No. 11/145,678 (the '678 Application referred to above). As stated above, a preliminary amendment was filed in the '678 Application canceling claims 1-44, and setting forth method claims that clearly do not conflict with and are patentably distinct from the presently pending composition of matter claims. Applicants acknowledge the Examiner's statement in the Office Communication of December 16, 2005 that the double patenting rejection over the '678 application "will be withdrawn." As of February 7, 2005, however, Applicants have received no communication that the rejection has in fact been withdrawn. Accordingly, the rejection remains pending. This rejection is a new rejection not caused by the Applicants' action or inaction, as discussed above, and is thus an improper basis for making this action final. Moreover, the rejection is facially incorrect due to the nature of the preliminary amendment in the '678 Application. The Examiner is requested to withdraw both the obviousness-type double

patenting rejection over copending Application No. 11/145,678 and the finality of the present action.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejected claims 37-44 and 46 under 35 U.S.C. § 103(a) as being unpatentable over Johnson & Johnson or Patel taken with G.B. 1454055 ("055") and Smith (U.S. Patent No. 3,671,280) ("Smith").

Applicants agree with the Examiner that neither of the primary references disclose cross-linked dextran beads. Office Action at page 4. However, Applicants disagree that either of the primary references renders the presently amended claims patentably obvious in view of the secondary references, '055 and Smith. Applicants will first discuss the secondary '055 reference, followed by the secondary Smith reference.

The Examiner referred to Example 5 of the '055 reference. However, Example 5 of the '055 reference does not disclose cross-linked dextran beads on a particular side of a gauze matrix. Instead, Example 5 discloses mixing crosslinked dextran particles with paper pulp and water. According to Example 5, "the fibres of the paper pulp were uniformly distributed between the crosslinked dextran particles." GB '055 at page 8, lines 63-65 (Emphasis added). It is apparent that crosslinked dextran beads were mixed with paper pulp in Example 5 and that the resulting product did not consist essentially of cross-linked dextran beads on a particular side. Nothing in the remainder of the '055 reference teaches or suggests that Johnson & Johnson or Patel should be modified to arrive at a wound dressing consisting essentially of cross-linked dextran beads on a particular side of the gauze. In view of the above, the combination of Johnson & Johnson or Patel taken with the '055 reference does not teach or suggest the presently claimed invention.

The Smith reference is similarly deficient, because Smith does not does disclose cross-linked dextran beads. Instead, Smith discloses high molecular weight dextran, which is different from cross-linked dextran beads. Compare '055 at page 1, lines 52-65 with Smith at column 3, lines 60-65, see, e.g., de Belder. Smith describes plaster of Paris compositions that may include high molecular weight dextran for, e.g., for improving the strength and moisture resistance of

casts. In determining whether art is analogous in an obviousness rejection, it must be determined (1) whether the reference is within the field of the inventor's endeavor; and (2) if not, whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *See In re Deminski*, 796 F.2d 436 (Fed. Cir. 1986). The claimed invention and a reference can be in the same field of endeavor if they have essentially the same function and structure. *Id.* Here, Smith is non-analogous art, as the preparation of plaster of Paris casts is not reasonably pertinent to the preparation of hemostatic wound dressings, and the claimed invention and the reference (plaster of Paris casts) do not have essentially the same function and structure. Thus, while a plaster of Paris cast is useful to set broken bones, one having ordinary skill would not have expected that plaster of Paris technology is relevant to compositions designed to stop bleeding.

Moreover, even if Smith were analogous art, Smith provides no teaching or suggestion that one having ordinary skill in the art should modify the compositions of the primary references to include cross-linked dextran beads. Smith points out that non cross-linked dextran results in a plaster of Paris cast that is more water-resistant (hydrophobic). Smith at column 4, lines 1-15. The Examiner has not explained how the disclosure of a water-resistant plaster of Paris cast would lead one of ordinary skill to use that disclosure to stop bleeding. In addition, a non cross-linked dextran having a molecular weight of about 70,000, designated Dextran 70, is used as a plasma volume expander. See, e.g., de Belder, Dextran, Amersham Biosciences AB (2003) at pages 7 and 31. Since non cross-linked dextrans such as Dextran 70 are plasma volume expanders, one of ordinary skill would not have expected the high molecular weight non cross-linked dextran of Smith to promote blood coagulation. Instead, one of ordinary skill might have expected that the high molecular weight non cross-linked dextran of Smith would prevent coagulation. Thus, the disclosure of Smith would have suggested to one of ordinary skill that non cross-linked dextran should be avoided and should not be used to modify Johnson & Johnson or Patel.

Motivation to Combine

The Examiner notes that motivation for combining references can come from the nature of the problem to be solved or the knowledge of one of ordinary skill in the art. Office Action at page 6. The Examiner is correct. "The suggestion or motivation to combine references does not have to be stated expressly; rather it may be shown by reference to the prior art itself, to the nature of the problem solved by the claimed invention, or to the knowledge of one of ordinary skill in the art." Medical Instrumentation and Diagnostics Corp v. Elekta AB, 344 F.3d 1205, 1221-22 (Fed. Cir. 2003).

However, a teaching, suggestion or motivation must come from somewhere. That is, there must be some reason for one of ordinary skill in the art to select the teachings of separate references and combine them to produce the claimed combination. As stated in Interconnect Planning; "[w]hen prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself." Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985). "[T]he test of whether it would have been obvious to select specific teachings and combine them as did the applicant must still be met by identification of some suggestion, teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention." In re Dance, 160 F.3d 1339, 1343 (Fed. Cir. 1998).

Here, it appears that the Examiner and Applicants agree there is no specific teaching or suggestion in the references themselves to combine them and produce the claimed invention. The remaining question then is whether there is any reason to select the cited references and combine them, i.e., whether a reason has been identified based on, e.g., the nature of the problem solved by the claimed invention or knowledge of one of ordinary skill in the art.

The nature of the problem solved by the presently claimed invention is staunching bleeding from severe trauma injury and surgery. The nature of the problem solved by Johnson & Johnson or Patel is similar.

However, the nature of the problem solved by the '055 reference is cleansing of fluid-discharging skin surfaces, e.g., foot sores, skin burns, and pressure sores. See '055 at page 7,

Examples 1-4. The only basis provided as to why one of ordinary skill would combine the '055 reference with one of the primary references is in Example 5, page 8, line 38. Office Action at pages 4 and 7. The '055 reference states here that "[p]articles produced in accordance with the invention can with advantage be incorporated in an inert material having no chromatographic effect, or only a slight effect, in an aqueous environment, for example fine paper pulp, cotton fabric and macroporous plastics." '055 at page 8, lines 33-39. It is apparent that this sentence suggests incorporation of particles, not particles on one side. The Examiner reasons that one of ordinary skill would select this sentence from a skin sore reference and modify one of the primary references for "the expected benefit [from a cross-linked polysaccharide] of obtaining a dry, removable wound dressing which is more pliable and more easily removable and which has hemostatic properties..." Office Action at page 6. However, one of ordinary skill would not have known that cross-linked dextran beads possessed hemostatic properties based on the '055 reference. This teaching is only found in Applicant's specification. That is, hindsight has been used to construct an obvious argument with respect to the '055 reference.

The nature of the problem solved by Smith is plaster of Paris bandages with improved strength, water resistance and physiological properties. See, Smith at Title. The only basis provided as to why one of ordinary skill would combine Smith with one of the primary references is that Smith teaches the use of high molecular weight dextran. Office Action at page 5-6. Applicants agree that high molecular weight dextran is old and known in the art. See, e.g., de Belder at page 23. Furthermore, cross-linked dextran is old and known in the art. See, e.g., de Belder at pages 36-37. However, high molecular weight dextran is different from cross-linked dextran. The Examiner has not identified a reason why one of ordinary skill would select the disclosure of high molecular weight dextran from a plaster cast reference and then decide to modify one of the primary references to solve the problems of promoting hemostasis. Applicant submits that the only reason one would do so is found in Applicant's specification and not in the prior art. That is, hindsight has been used to construct an obvious argument with respect to the Smith reference.

The knowledge of one of ordinary skill in the art would not have lead to the claimed invention. The Examiner has recognized that there must be some reason why one of ordinary

skill would be motivated to combine the primary and secondary references. The reason given here is for "their known art specific properties, which are as hemostatic agents in different combination . . ." Office Action at page 6. However, one of ordinary skill in the art would not have known that cross-linked dextran beads possessed hemostatic properties based on the disclosures of Johnson & Johnson, Patel, the '055 reference, or Smith. Instead, the only objective teaching that one of ordinary skill should use cross-linked dextran beads for hemostasis is found in Applicant's specification.

In view of the above, no objective reason, suggestion or motivation has been identified in the prior art to combine the references. Instead, the Examiner has use hindsight, picking and choosing amongst the prior art to construct an argument that one of ordinary skill was aware that cross-linked dextran beads had hemostatic properties and, therefore, one should modify the primary reference.

Expectation of Success

The Examiner alleged that one of ordinary skill would have had a reasonable expectation of success in substituting the dextran components of the '055 and Smith references for the alginate materials of the primary references because "both of these polysaccharide polymers have suitable properties for use in gauze coated bandages, such as being hemostatic and preventing adhesion." Office Action at page 5. Applicants disagree.

The '055 reference and Smith taken together disclose different dextrans, and if one of ordinary skill would have expected that substituting either dextran will do, then an objective basis must be presented as to why one of ordinary skill would have had that expectation.

The '055 reference refers to cross-linked dextran particles. See, e.g., '055 at page 3, lines 1-4 and 36. The '055 reference hypothesizes that cross-linked dextran particles move fibrinogen away from a discharging skin surface and keep the skin surface free from coagulation. See, e.g., '055 at page 2, lines 43-47 and lines 86-92. The Smith reference refers to high molecular weight dextran. See, Smith at column 3, lines 60-65. Smith reports that high molecular weight dextran makes stronger, more hydrophobic casts. See, e.g., Smith at column 4, lines 1-15.

The properties of different dextrans as discussed in the '055 reference and Smith would have created considerable uncertainty for one of ordinary skill and would not have given a reasonable expectation of success that substituting any dextran for alginate would have made a successful hemostatic wound dressing. In fact, one having ordinary skill in the art would not have known what to expect, given that crosslinked dextran beads might have prevented coagulation, based on the statements in the '055 reference, while high molecular weight dextran might have repelled aqueous materials such as blood, based on the statements in Smith. Thus, even if it is assumed that the references provide motivation, one of ordinary skill in the art would have had no reasonable expectation of success.

Unexpected Properties

The Examiner dismisses Applicants' evidence regarding the hemostatic properties of the claimed invention by asserting that "[i]n response to applicant's extensive arguments regarding the unexpected hemostatic properties of the invention, it is noted that whether or not a composition comprising a paper pulp or cotton coated with dextran beads as taught by '055 is hemostatic or not is a property of the composition whether it is recognized by the inventors thereof or not. Applicant has not demonstrated unexpected properties for the composition as claim designated to patentably distinguish it over the references." Office Action at page 7.

The Examiner has mischaracterized the '055 reference. The Examiner asserts that the '055 reference teaches paper pulp or cotton coated with dextran beads, but has failed to point to any such teaching in the '055 reference. The '055 reference refers to material mixed with, or incorporated in, fibrous materials such as cellulose fibers or paper pulp. '055 at page 6, lines 69-79. The '055 reference also discusses material enclosed between layers of paper, cotton fabric or inert plastics, and states that the fabric "must, of course, have such a mesh size that particles cannot pass through the meshes" '055 at page 6, lines 101-106. The '055 reference discusses applying cross-linked dextran beads to a skin sore, and then covering the sore with a gauze bandage. See, GB '055 at page 7, lines 8-28. The '055 reference also indicates that when crosslinked dextran particles and paper pulp were mixed, the paper pulp fibres were uniformly distributed between the crosslinked dextran particles. GB '055 at page 8, lines 33-65. In view of

the above, the '055 reference does not disclose a hemostatic wound dressing consisting essentially of cross-linked dextran beads on a particular wound-contacting side of a gauze matrix, and Applicants' evidence of unexpected properties stands unrebutted.

Secondary Considerations

Applicants note that so-called "secondary" considerations such as failure of others must be given due weight by the Examiner during *ex parte* prosecution. *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983). Here, the Examiner has failed to give due weight to the evidence submitted by Applicants.

The Examiner urged that the references put forth are directed to hemostatic methods rather than to the composition per se, as claimed, and for this reason the arguments failed to persuade. Office Action at page 7. Applicants believe that is exactly the reason the references are persuasive. I.e., the references put forth by Applicants relate to methods to promote hemostasis, yet they use compositions different from those presently claimed. This means there has been a failure of those making hemostatic wound dressings and working with cross-linked dextran beads to appreciate the hemostatic effect of cross-linked dextran beads. Current compositions for stopping bleeding are different from the presently claimed compositions. See, e.g., Pusateri et al., J. Trauma 55:518-526 (2003); Sondeen et al., J. Trauma 54:280-285 (2003); Crosseal™ Fibrin Sealant (2003); and Tisseel™ VH Fibrin Sealant Product Label (2003). These articles were submitted in the IDS of September 2, 2005. Cross-linked dextran beads have been known since the 1960s. See, e.g., Downstream Thirty, Amersham Pharmacia Biotech (1999) in the IDS submitted herewith. Yet, cross-linked dextran beads are currently used by themselves to treat cutaneous ulcers and wounds under the trade name Debrisan®. See, e.g., de Belder at page 34 and references cited therein.

Furthermore, the age of the cited art is relevant to the obviousness inquiry. Applicants recognize that the mere age of a reference is not persuasive without evidence that the art tried and failed to solve the problem. *In re Wright*, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA, 1977). See, MPEP § 2145. Here, there is evidence that the art tried and failed to arrive at the

solution of cross-linked dextran beads. According to Pusateri et al., only a composition comprising fibrinogen and thrombin was effective in achieving hemostasis and reducing blood loss. Pusateri et al., J. Trauma 55:518-526 (2003). These are the primary active ingredients currently available for hemostasis use. Crosseal™ Fibrin Sealant (2003); and Tisseel™ VH Fibrin Sealant Product Label (2003). Clearly, the art is trying to make hemostatic compositions yet has failed to make compositions consisting of essentially cross-linked dextran beads and a gauze matrix.

Johnson & Johnson was published in 1949. Patel was published in 1995. The '055 reference was published in 1976. Smith was published in 1972. The cited art failed to make the claimed compositions. The current art is not using crosslinked dextran beads to promote hemostasis. The failure of others to teach or suggest the claimed compositions is strong evidence for patentability.

In view of the above, Applicants request that the rejection under 35 U.S.C. § 103(a) in view of J&J or Patel taken with GB '055 and Smith be withdrawn.

Applicant : Kent Cochrum et al.
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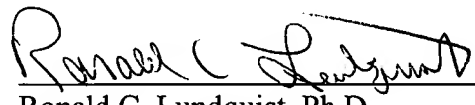
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CONCLUSION

Applicants assert that all claims are in condition for allowance, which action is requested. Enclosed is \$60.00 check for the Petition for Extension of Time fee (1 month), a \$395.00 check for the Request for Continued Examination, and a Supplemental Information Disclosure Statement. Please apply any other charges or credits to deposit account 06-1050.

Submitted,

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